--FREEZE-DRIED CONTROLLED RELEASE COMPOSITIONS AND METHODS OF MAKING SAME--

IN THE CLAIMS:

Kindly amend the claims as follows:

D1

1. A freeze-dried composition comprising:

(a) a sustained release layer comprising:

(i) a water-soluble polymer; and

(ii) a first pharmaceutically active agent; and

(b) a fast release layer comprising:

(i) a matrix forming agent; and

(ii) a second pharmaceutically active agent;

said composition being made by the process comprising:

(a) adding said water-soluble polymer and said first pharmaceutically active agent to water to form a first aqueous solution;

(b) adding said matrix forming agent and said second pharmaceutically active agent to water to form a second aqueous solution;

(c) combining said first and said second aqueous solutions in a container to form a combined solution;

(d) rapidly freeze-drying said combined solution; and

(e) lyophilizing said combined solution.

D2

7. A composition as defined in claim 1, wherein the sustained release layer further comprises a fatty acid.

8. A composition as defined in claim 7, wherein the fatty acid is a hydrogenated vegetable oil.

D3

56. A freeze-dried pharmaceutical composition comprising;

(a) a sustained release layer comprising:

(i) a water-soluble polymer; and

(ii) a first pharmaceutically active agent; and

(b) a fast release layer comprising:

(iii) a matrix forming agent; and

(iv) a second pharmaceutically active agent

said composition being made by the process comprising:

(a) adding said water-soluble polymer and said first pharmaceutically active agent to water to form a first aqueous solution;

(b) adding said matrix forming agent and said second pharmaceutically active agent to water to form a second aqueous solution;

(c) combining said first and said second aqueous solutions in a container to form a combined solution;

(d) rapidly freeze-drying said combined solution; and

(e) lyophilizing said combined solution.

65. A freeze-dried pharmaceutical composition comprising:

(a) a sustained release layer comprising:

(i) a water-soluble polymer selected from the group consisting of celluloses, cellulose ethers, polycarboxylated vinyl polymers, polyurethanes, gelatins, polysaccharide gums, seed gums, crosslinked [laginate] alginate gum gels and any combination of the foregoing; and

(ii) a first pharmaceutically active agent selected from the group consisting of metronidazole, miconazole nitrate, terconazole, chlorpheniramine maleate, pseudophedrine, dextromethorphan, meclizine dihydrochloride, haloperidol, albuterol sulfate, dimenhydrinate, benzodiazepines, and any combination of any of the foregoing; and

(b) a fast release layer, comprising:

(i) a matrix forming agent selected from the group consisting of animal and vegetable protein derivatives, gums, polysaccharides, alginates, carboxymethylcelluloses, carrageenans, dextrans, pectins, polyvinylpyrrolidone, polyacrylic acid, polypeptide/protein complexes, sugars, inorganic salts, amino acids having from about 2 to about 12 carbon atoms, and any combinations of any of the foregoing; and

(ii) a second pharmaceutically active agent, selected from the group consisting of metronidazole, terconazole, miconazole nitrate, chlorpheniramine maleate, pseudophedrine, dextromethorphan, meclizine dihydrochloride, haloperidol, albuterol sulfate, dimenhydrinhate, benzodiazepines, and any combination of any of the foregoing;

said composition being made by the process comprising:

(a) adding said water-soluble polymer and said first pharmaceutically active agent to water to form a first aqueous solution;

(b) adding said matrix forming agent and said second pharmaceutically active agent to water to form a second aqueous solution;

(c) combining said first and said second aqueous solutions in a container to form a combined solution;

(d) rapidly freeze-drying said combined solution; and

(e) lyophilizing said combined solution.

D4 Cont'd

66. A freeze-dried pharmaceutical vaginal suppository composition comprising:

(a) a sustained release layer, comprising:

(i) from about 5 to about 70% by weight of a water-soluble polymer;

(ii) from about 15 to about 95% by weight of a first pharmaceutically active agent; and

(b) a fast release layer, comprising:

(i) from about 0.5 to about 15% by weight of a matrix forming agent; and

(ii) from about 85 to about 99.5% by weight of a second pharmaceutically active agent;

said composition being made by the process comprising:

(a) adding said water-soluble polymer and said first pharmaceutically active agent to water to form a first aqueous solution;

(b) adding said matrix forming agent and said second pharmaceutically active agent to water to form a second aqueous solution;

(c) combining said first and said second aqueous solutions in a container to form a combined solution;

(d) rapidly freeze-drying said combined solution; and

(e) lyophilizing said combined solution.

Kindly add the following claims:

D5

67. A composition according to claim 1 wherein the first and second aqueous solutions are added together in a ratio of about 1:1.

REMARKS

This Amendment Under 37 CFR 1.116 is respectfully submitted in response to the Final Rejection rendered February 4, 2002. It is timely in view of the Petition for Extension of Time submitted concurrently herewith and in view of the fact that July 4, 2002 is a holiday. Claims 1, 56, 65 and 66 have been amended to indicate the method of making the